



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/999,752	06/04/97	MILLAR	F 7755/0D276

BERT J LEWEN
DARBY & DARBY
305 THIRD AVENUE
NEW YORK NY 10022

HM12/0830

EXAMINER

BAWA, R

ART UNIT	PAPER NUMBER
1619	20

DATE MAILED: 08/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/999,752	Applicant(s) Millar
	Examiner Mr. Raj Bawa	Art Unit 1619
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.		
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.		
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.		
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).		
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jul 24, 2000</u>		
2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1 and 3-22</u> is/are pending in the application.		
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1 and 3-22</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:		
1. <input type="checkbox"/> Certified copies of the priority documents have been received.		
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.		
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).		
Attachment(s)		
15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		
18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
20) <input type="checkbox"/> Other: _____		

Art Unit: 1619

Detailed Action

(1) In view of the letter from the PTO re. "Withdrawal of Abandonment" (Paper No. 20), the final rejection mailed on 12/02/99 has been vacated. Below appears a new office action:

(2) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(I) The claims do not recite proper Markush language. It is suggested that the language "selected from the group consisting of... and ..." be recited throughout the claims.

(ii) The phrase "similar molecule" is vague and indefinite in the context employed because the "similar molecule" is neither defined in the specification nor would it be apparent to one of ordinary skill in the art. Furthermore, it is a relative term. It is unclear as to how the molecule is similar to beclomethasone. Is it related "functionally" or "structurally"? As a result, the metes and bounds of the patent protection desired are unascertainable. (Note that the word "molecule" is misspelled in claim 4).

(iii) Please substitute the phrases "such medicament" and "such formulation" in the claims with the conventional language "said medicament" and "said formulation" respectively.

Art Unit: 1619

It view of the above statements, it is the Examiner's position that the claims do not meet the threshold requirement of clarity and precision and are not in compliance for definiteness of 35 U.S.C. 112, second paragraph. Note that definiteness of the claims is important to allow others who wish to enter the marketplace to ascertain the boundaries of protection that are provided by the claims (*Ex parte Kristensen* 10 USPQ2d 1701, 1703).

(3) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Purewal et al. (U.S.P. 5,225,183).

Purewal et al. disclose aerosol compositions that contain particulate medicament, a fluorocarbon propellant (e.g., HFC 134a), polar co-solvent (e.g., ethanol), etc. This is the exact scope of the above-mentioned claims. Note that Purewal discloses all claimed medicaments (col. 5, line 52- col. 6, line 35). The claimed range (6-25% w/w) of polar co-solvent (ethanol) is also identically disclosed by Purewal et al. (e.g., see Examples). The applicants recite the open language "comprising" along with the phrase "substantially free of surfactant." As stated previously, this phrase does not exclude the presence of a surfactant from the applicant's aerosol formulation. Furthermore, note that this phrase is not defined in the applicant's specification. Additionally, there is no statement in the specification or evidence of record that establishes that

Art Unit: 1619

minor amounts of conventional surfactant(s) are excluded from the claimed aerosols. Therefore, Purewal's surfactant is not excluded from the claimed aerosols. Clearly, the phrase "substantially free of surfactant" is not equivalent to "free of surfactant." Note that the instant claims are directed to a composition and since Purewal et al. disclose all claimed ingredients, the two compositions are identical. Note that in this regard, it is well established that the claims are given the broadest interpretation during examination; and (ii) references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 U.S.P.Q. 545 (CCPA 1969).

The incorporation of the claimed aerosols into conventional aerosol canisters is inherent to the aerosols themselves since this is the standard mode of delivery in this art.

In light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been anticipated within the meaning of 35 U.S.C. 102(b).

No claims are allowed.

(4) The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(5) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703) -308-2423. The examiner can normally be reached on Tuesday through Friday from 7:30 AM to 6:00 PM.

Art Unit: 1619

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703)-308-2328. The fax phone number for the organization where this application or proceeding is assigned is (703)-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235.



RAJ BAWA, Ph.D.
PRIMARY EXAMINER